UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: August 3, 2021

SUBJECT: Efficacy Review for Envirocleanse-A,
EPA Reg. No. 85134-1
E-submission No. 62008
Action Case Code: 00295716

FROM: Atinuke Onyonyor
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: 6/1/2021

THRU: Sophie Nguyen
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: August 3, 2021

TO: Dan Halpert/Aline Heffernan, Acting PM Team 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Envirocleanse, LLC.

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hypochlorous acid	0.025%
Other Ingredients	99.975%
Total	100.000%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Liquid

Submission type: Label Amendment

Currently registered efficacy claim(s): Ready-to-use disinfectant (bactericidal and virucidal) non-food contact surface sanitizer, 24-hour residual sanitizer and fungistat

Requested action(s): Applicant is requesting a label amendment to include the addition of electrostatic sprayer (ESS) as an additional method of application for Envirocleanse-A (EPA Reg. No. 85134-1). Applicant has submitted 2 non-GLP confirmatory data studies to bridge efficacy data from the existing product and a video for confirmation of the established dwell time.

Documents considered in this review:

- Cover letter from applicant to EPA dated 3/26/2021
- Letter in Response to Technical Screen from applicant to EPA dated 4/9/2021
- Proposed label (Version 18) dated March 2021
- Data Matrix (EPA Form 8570-35) dated 3/26/2021
- 2 efficacy studies (MRIDs 51527801 and 51527802)
- Confidential Statement of Formula (EPA Form 8670-4) dated 2/9/2021

II AGENCY STANDARDS

Instructions for Adding Electrostatic Spray Application Directions for Use to Antimicrobial Product Registrations:
https://www.epa.gov/pesticide-registration/expedited-review-adding-electrostatic-spray-application-directions-use

III PROPOSED DIRECTIONS FOR USE

Electrostatic Sprayers
Spray droplet particle size (regardless of the ability to change nozzles that impact particle size) should be limited to volume median diameter (VMD) ≥40 µm. Place the electrostatic spray function in the ON position for electrostatic spray models that have the functionality to toggle ON/OFF. Bystanders and pets must not be in the room during application. Minimum spray distance is 6 inches, maximum spray distance is 8 inches, from application equipment spray nozzle tip to the treated surface. The product's "contact time" (i.e. visible surface wetness) on the treated surface is 10 minutes and the product should be reapplied if the surface dries before the contact time is achieved. When applying, use an N95 filtering facepiece respirator or half face respirator with N95 filters.

III STUDY SUMMARIES

1.	**MRID**	51527801		
Study Objective		Disinfectant – bactericidal		
Study Title		Germicidal Spray Products as Disinfectants Using Electrostatic Spraying		
Testing Lab; Lab Study ID		bioX, LL; Project # SS-GS-BIOX-JUN20		
Experimental Start Date		9/4/2020	**Study Completion Date:**	10/12/2020
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538) 0.01 mL culture inoculated		
Test Method		Modified Germicidal Spray Method Protocol # BIOX-QP-GSPT-001-01 *(copy provided)*		
Application Method		Ready-to-Use Electrostatic Sprayer, applied at a distance of 6-8 inches until throughly wet		
Test Substance Preparation	**Name/ID**	Envirocleanse-A		
	Lots **☐ 1 ☒ 2 ☐ 3**	Batch 2: 330 FAC PPM (HOCl @ 0.025%) Batch 4: 330 FAC PPM (HOCl @ 0.025%)		
	Preparation	Tested concentration: Nominal Tested Dilution: Ready-to-use @ 338 FAC PPM (HOCl @ 0.025%) Diluent: N/A		
Soil load		5% FBS		
Carrier type, # per lot		25 mm x 25 mm glass slides; 10 carriers/lot		
Test conditions		Contact time: 10 minutes Temperature: 20 ± 2°C Relative humidity: 18%		
Neutralizer		20 mL Letheen Broth with 0.07% Lecithin, 0.5% Tween 80 and 0.05% Catalase		
Incubation Conditions		*Pseudomonas aeruginosa*: 48-54 hours at 36 ± 1°C *Staphylococcus aureus*: 48-54 hours at 36 ± 1°C		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol deviations No protocol amendments Addendum to Final Study Report to reflect corrections to the table information per Section C on page 5, Section D on page 6, and within Attachment 1, on page 14 in the first line information as to the efficacy of the Test Substance in sub-paragraph B table information (for Lower Certified Limits (LCL) row and MSDS/ Certificate of Analysis row). Attachment #2 has been added to page 17 which is inclusive of Envirocleanse's Declaration of Certificate of Authenticity and Conformity. Dwell time (Wetness Testing) Control: Consistent with MLB SOP MB-31 for Gravimetric and Physical Wetness Determination, Confirmation of dwell time establishment using the electrostatic sprayer and Envirocleanse-A is available video confirmation for the established dwell time and also confirmed/checked gravimetrically.		

2.	**MRID**	51527802		
Study Objective		Disinfectant – virucidal		
Study Title		Virucidal Hard-Surface Efficacy Testing Using Electrostatic Spraying		
Testing Lab; Lab Study ID		bioX, LL; Project # BIOX-EC-JUN20-17-01		
Experimental Start Date		9/3/2020	**Study Completion Date:**	9/12/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Feline Calicivirus (FCV), Strain: F9, ATCC VR-782 0.4 mL culture inoculated		
Indicator Cell Cultures		CrFK cells (ATCC CCL-94)		
Test Method		Modified Germicidal Spray Method Protocol # *(copy provided)*		
Application Method		Ready-to-Use Electrostatic Sprayer, applied at a distance of 6-8 inches until throughly wet		
Test Substance Preparation	**Name/ID**	Envirocleanse-A		
	Lots **☐ 1 ☒ 2 ☐ 3**	Batch 2: 330 FAC PPM (HOCl @ 0.025%) Batch 4: 330 FAC PPM (HOCl @ 0.025%)		
	Preparation	Tested concentration: Nominal Tested Dilution: Ready-to-use @ 338 FAC PPM (HOCl @ 0.025%) Diluent: N/A		
Soil load		5% FBS		
Carrier type, # per lot		Sterile glass petri dishes; 2 carriers/lot		
Test conditions		Contact time: 10 minutes Temperature: 18 ± 2°C (actual 18.8°C) Relative humidity: 18% ± 2%		
Neutralizer		RPMI 1640 + 10% FBS + 0.5% $Na_2S_2O_3$		
Incubation Conditions		Feline Calicivirus: 7 – 9 days at 36 ± 2°C with 5 ± 1% CO_2		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		No protocol deviations No protocol amendments Dwell time (Wetness Testing) Control: Consistent with MLB SOP MB-31 for Gravimetric and Physical Wetness Determination, Confirmation of dwell time establishment using the electrostatic sprayer and Envirocleanse-A is available video confirmation for the established dwell time and also confirmed/checked gravimetrically.		

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Carrier Pop. (Avg CFU/Carrier)
		Batch 4	Batch 2	
10-minute contact time, ready-to-use liquid ESS; 5% FBS				
51527801 (non-GLP)	*Staphylococcus aureus* ATCC 6538	0/10	0/10	2.1×10^6
	Pseudomonas aeruginosa ATCC 15442	0/10	0/10	2.3×10^6

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Batch 4	Batch 2	
10-minute contact time, ready-to-use liquid ESS; 5% FBS					
51527802 (non-GLP)	Feline Calicivirus (FCV), Strain: F9, ATCC VR-782	Cytotoxicity	10^{-2}	10^{-2}	5.34 log_{10}
		Complete inactivation	10^{-3} to 10^{-7} dilution*	10^{-3} to 10^{-7} dilution*	
		Log_{10} $TCID_{50}$/carrier	≤ 1.13 log_{10}	≤ 1.10 log_{10}	
		Log Reduction	≥ 4.22 log_{10}	≥ 4.25 log_{10}	

*Dilution refers to the fold of dilution from the virus inoculum. Post neutralized sample was considered the 10^{-1} dilution.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Spray & Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51527801 (non-GLP)	Disinfectant, Bactericidal activity – Electrostatic Sprayer	Hard, non-porous surfaces (glass slides)	Ready-to-use Electrostatic Sprayer	Spray from 6-8 inches away from surface until thoroughly wet & 10 minutes contact time	5% FBS	N/A	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442	**Yes**
51527802 (non-GLP)	Disinfectant, Virucidal activity – Electrostatic Sprayer	Hard non-porous surface (glass petri dishes)	Ready-to-use Electrostatic Sprayer	Spray from 6-8 inches away from surface until thoroughly wet & 10 minutes contact time	5% FBS	N/A	Feline calicivirus Strain: F9 ATCC VR-782	**Yes**

VI LABEL COMMENTS

Label Date: Version 18 dated March 2021

1. The proposed label claims that the product, Envirocleanse-A (EPA Reg. No. 85134-1), when used with an electrostatic sprayer as directed from 6-8 inches on visibly cleaned hard, non-porous surfaces for the indicated contact time on the label is an effective disinfectant against the following bacteria:

   10-minute contact time:
   Pseudomonas aeruginosa (ATCC 15442)
   Staphylococcus aureus (ATCC 6538)

   These claims are **acceptable** at this time as they are supported by the submitted data. However, the following should be noted:
   - The wetness testing study consistent with MLB SOP MB-31 was not submitted for review. Only wetness testing videos were submitted and evaluated for duration of wetness. The registrant should plan to submit wetness testing study using the ESS in a future submission for evaluation.
   - The agency recommends testing at the minimum and maximum distance claimed on the label per the electrostatic sprayer guidance. While 6-8 inches is a range and only one distance was tested, for future ESS testing, please consult with the agency prior to testing to establish the distance for testing or whether a range is acceptable.

2. The proposed label claims that the product, Envirocleanse-A (EPA Reg. No. 85134-1), when used with an electrostatic sprayer as directed from 6-8 inches on visibly cleaned hard, non-porous surfaces for the indicated contact time on the label is an effective disinfectant against the following virus:

   10-minute contact time:
   Feline calicivirus Strain: F9 (ATCC VR-782)

   These claims are **acceptable** at this time as they are supported by the submitted data. However, the following should be noted and/or submitted:
   - The wetness testing study consistent with MLB SOP MB-31 was not submitted for review. Only wetness testing videos were submitted and evaluated for duration of wetness. The registrant should plan to submit wetness testing study using the ESS in future submission for evaluation.
   - The agency recommends testing at the minimum and maximum distance claimed on the label per the electrostatic sprayer guidance. While 6-8 inches is a range and only one distance was tested, for future ESS testing, please consult with the agency prior to testing to establish the distance for testing or whether a range is acceptable.

3. On page 6 of the proposed label, revise the table in the Emerging Pathogen Claim section to be as follows:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Norovirus (Feline Calicivirus as surrogate, ATCC VR-782)
Large, non-enveloped virus	Norovirus (Feline Calicivirus as surrogate, ATCC VR-782)

4. Make the following changes to the proposed label:
   a. Throughout the label, qualify floors with "finished" or "sealed".
   b. On pages 2 and 3 of the proposed label, under each applicable set of use directions, revise "wet" and descriptions of the contact time to "must remain visibly wet" for required contact time.
   c. On page 4 of the proposed label, under the use directions for Electrostatic Sprayer revise the statement "the product's 'contact time' (ie. visible surface wetness) on treated surfaces is 10 minutes…" to "the product must remain visibly wet on treated surfaces for 10 minutes…"
   d. On page 5 of the proposed label, toilets should be qualified to indicate exterior surfaces of toilets or the exposed areas in toilets (where water is not present).
   e. Under Optional Label Claims starting on page 7,
      i. The claim "works quickly" should be revised to "works quickly to clean" or similar. Quickly cannot be applied disinfection as there are contact times that are not considered quick.
      ii. References to uses around the house/home/kitchen/bathroom should specify on hard, non-porous surfaces.
      iii. Remove "germ killer" this implies heightened efficacy. It may be revised to "kill germs" with "germs" being qualified to reference the bacteria and viruses approved.
      iv. Remove "fast acting" to describe sanitization. The contact time for food contact surface sanitization is a requirement for testing.
   f. Under Disinfection claims starting on page 10,
      i. Spell out the binomial names for the bacteria in the marketing claims (e.g., Salmonella should be Salmonella enterica, Staph to Staphylococcus aureus).
      ii. All claims pertaining to SARS-CoV-2 should indicate effectiveness on hard, non-porous surfaces.
      iii. Every instance where "eliminate" or "elimination" is used in reference to germs and/or bacteria, indicate 99.9% after these terms so as not to imply complete kill.
      iv. Remove "common household bacteria" as the agency does not have defining criteria for this. Alternatively, this claim can be qualified to reference the bacteria tested and approved.
      v. Qualified every instance of "germs".
      vi. Insert "hard, non-porous" between "treated surfaces" in the claim "Can help reduce the risk of cross-contamination on treated surfaces."
      vii. Revise "Can reduce the spread of illness-causing (kitchen) bacteria on hard, nonporous surfaces" to "Can reduce the spread of pathogens on treated hard, non-porous surfaces." Claims implying effectiveness against illnesses are not permitted.

viii. References to uses around the house/home/kitchen/bathroom should specify on hard, non-porous surfaces.
ix. Claims referencing food pathogens and poop (fecal matter) germs should indicate effectiveness on hard, non-porous surfaces. Germs should be qualified.
x. Qualify every claim referencing germs, germicide, or germicidal.
xi. Location claims, such as around the house/home/kitchen, etc., foodservice settings, workplace, daycare facilities, hospital, etc. should indicate effectiveness on hard, non-porous surfaces.
xii. "Multi-surface" should be revised to "multi hard, nonporous surfaces".
xiii. Revise the claim "Stop the spread of germs, spray on animal chew toys" to "reduce the spread of germs on hard, non-porous surfaces, spray on animal chew toys." Qualify "germs".
xiv. Revise "Surface germ (ELIMINATOR) (KILLER)" to "kill germs on hard, non-porous surfaces." Qualify germs.
xv. Every claim for "virus", "virucide", "virucidal" should be qualified to reference the viruses tested and approved.
xvi. Revise "COVID-19 virus" to "SARS-CoV-2, the virus that causes COVID-19 on hard, non-porous surfaces". COVID-19 virus is not the proper name of the virus. Remove 2019 Novel Coronavirus as this name is replaced with SARS-CoV-2. Indicate effectiveness on hard, non-porous surfaces in the claim and other claims referencing SARS-CoV-2.
xvii. Revise the claim "(Now) tested (and proven (effective)) to help (reduce the spread of) (the) (COVID-19 virus) (SARS-CoV-2) (2019 Novel Coronavirus)" as suggested above; additionally, "reduce the spread of…" should be revised to "reduce the spread of… on treated, hard, non-porous surfaces."

g. Under Sanitization claims on page 17 and beyond, please indicate effectiveness on hard, non-porous surfaces.
h. On page 20 of the proposed label, qualify surfaces such as stovetops, ovens, and microwaves with "allow surface to come to room temperature."